Cluster Investigation Team:

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Overview

In response to continuing community concern about a possible excess of perinatal deaths for the first six months of 1999 in Cowlitz County, we conducted an investigation to determine whether a cluster of deaths existed. We concluded that the apparent elevations in perinatal deaths were attributable to an elevation in late fetal deaths occurring in the category of 28+ weeks gestation. We found no patterns which could explain this elevation. We recommend further enhanced monitoring of these reproductive outcomes. Infant and fetal deaths are tragic losses for the family and the community. We support the wide range of public health programs aimed at promoting healthy mothers and healthy babies, and recommend that the performance of these measures be assessed.

Background

The background for this report, including a description of the formation of the cluster investigation team, the case definition, use of existing mortality data, and methods for case ascertainment and confirmation, is contained in the previous report "Report on cluster investigation: Cowlitz perinatal deaths Jan-Mar 1999", available on the World-Wide Web at http://www.doh.wa.gov/EHSPHL/Epidemiology/NICE/. The methods used for this current report are identical with those used in the prior report.

Data analysis

Data analysis consisted of comparison of the observed number of deaths to the expected number of deaths, using the following method. A "Poisson 95% Confidence Interval" is created around the observed number. This confidence interval (CI) is an indicator of the uncertainty which is found when small numbers are examined. This statistic is then compared to the expected number. If the range around the observed number does not include expected number, then we label the result "statistically significant" and we conclude that the observed number differs from that expected. If the range around the observed number includes expected number, then we label the result "not statistically significant" and we conclude that the observed number does not differ from that expected.

At the conclusion of case ascertainment and confirmation, six infant deaths and eleven fetal deaths were found to meet the case definition. When all 17 perinatal deaths were considered together, the case series constituted a statistically significant cluster. Data

analysis of the perinatal deaths found a 95% CI around the observed number to be 9.9 to 27, a range which did not include the expected number of 7.9. The ratio of observed to expected (O/E) was 2.2, which is a modest elevation. We concluded that this elevation could be best understood by separate analysis of the infant and fetal deaths.

Data analysis of the six infant deaths found a 95% CI around the observed number to be 2.2 to 13, a range which included the expected number of 5.2. The O/E ratio was 1.2, which was not statistically significant. We concluded that the number of observed infant deaths for the period did not exceed that expected, and closed that portion of the investigation.

Data analysis of the eleven fetal deaths, however, found a statistically significant elevation. The 95% CI around the observed number was 5.5 to 20, a range which did not include the expected number of 2.7. The O/E ratio was 4.2, which is a substantial elevation. We concluded that the number of observed fetal deaths for the period exceeded the number expected, and thus, as in analysis of data from the first quarter of 1999, returned to the case definition stratification method to examine the influence of gestational age.

Information on the estimated gestational age of the fetal deaths was obtained, and it was found that of the eleven fetal death cases, three were in the category of 20-27 weeks gestation. For these three cases, the 95% CI around the observed number was 0.6 to 9, a range which included the expected number of 1.3, and the O/E ratio was 2.4, which was not statistically significant. We concluded that the number of observed fetal deaths in the category of 20-27 weeks gestation for the period did not exceed the number expected, and inferred that the known fluctuations in reporting were most likely responsible for the apparent increase.

These known fluctuations in reporting have another dimension which affected case ascertainment for this investigation: legal requirements for reporting differ between states. In Washington state, the reporting requirement starts at an estimated gestational age of 20 weeks. In Oregon, the reporting requirement is based both on estimated gestational age and the weight of the fetus at delivery. Consequently, a fetal death can be delivered in Oregon which meets the reporting requirement in that state (and thus generates a certificate), but does not meet the reporting requirement in Washington. This happened in early 1999, when a fetal death of a Cowlitz resident was recorded in Oregon with an estimated gestational age of less than 20 weeks, and the certificate was sent to Washington. This fatality was not included as a case for this investigation because it did not meet the case definition: the case definition was established mainly to allow comparison of current occurrence of fetal death with prior occurrence, in order to determine whether current occurrence differed from that seen in the past, and the historical data which comprised the basis of the comparison did not include any fetal deaths with an estimated gestational age of less than 20 weeks.

For one of the eleven fetal death cases, no estimated gestational age was stated. This is consistent with data statewide, where 7% of fetal death certificates lack information on estimated gestational age.

For the seven fetal death cases in the category of 28+ weeks gestation, the Poisson 95% CI around the observed number was 2.8 to 14, a range which did not include the expected number of 1.2. The O/E ratio was 5.8, which is a substantial elevation. We concluded that the number of observed fetal deaths in the category of 28+ weeks gestation for the period exceeded the number expected.

Because the number of observed cases exceeded the number of expected cases, we obtained copies of the eleven fetal death certificates, to look for common factors, such as in the cause of death information. Frequency distributions were prepared on demographic variables, environmental variables, biological variables, events during pregnancy, and outcome variables (Table). Review of these data by the team revealed no patterns.

Table of factors examined	
Demographic variables	Age of mother
	Race/ethnicity (mother)
	Education (mother)
	Marital status
	Payor of prenatal care
Environmental variables	Residence - city
	Residence - zip code
	Months at present address
	Calculated estimate of date of conception
Biological variables	Medical history
	Number of prior pregnancies
	Number of prior spontaneous terminations
	Number of prior induced terminations
	Number of live births
Events during pregnancy	Mother smoked
	Mother used alcohol
	Weight gain
	Month of entry into pre-natal care
	Labor & delivery
	Gestational age
Outcome variables	Cause (as stated)
	Congenital malformations
	Autopsy performed

Because no patterns emerged from analysis of the fetal death certificates, we decided to defer further investigation. It is standard practice, when patterns are apparent in a case series, to assemble a comparison group in order to determine whether those patterns are unusual. Such analyses, termed "case-control studies," reveal whether certain factors are associated with an outcome, though they do not explicitly establish causation. However,

when no patterns are evident in a case series, little can be gained from conducting such studies.

Conclusions and recommendations

In this investigation of Cowlitz fetal deaths, the cluster investigation team concluded that the apparent elevations in perinatal deaths were attributable to an elevation in late fetal deaths occurring in the category of 28+ weeks gestation. We found no elevation in infant deaths, and we concluded that the apparent elevation in early fetal deaths (20-27 weeks gestation) was understandable in terms of variation due to known fluctuations in reporting of early fetal deaths. We discovered no patterns in analyses of the death certificates for the fetal deaths, and thus the elevation remains unexplained.

The fact that all fetal deaths, when considered together, were elevated over the number expected, led the team to recommend further enhanced monitoring of these reproductive outcomes. This monitoring will include subsequent examination of the occurrence of fetal deaths during the remainder of 1999. To assist in this monitoring, we also recommend that the Cowlitz County Health Department work with the medical community to increase the proportion of fetal deaths which are autopsied.

The cluster investigation team proposes that the plan for monitoring be tailored to the phases of the investigation. Previously, active case ascertainment involved contacting vital statistics staff in two state health agencies and six local health agencies, with requests for special expedited handling of fetal death certificates. Normally, these certificates are filed with the Washington state Center for Health Statistics in batches, with up to several weeks lag between occurrence of the event and the filing; certificates from Oregon may have somewhat greater lag. In the next phase, we will use passive case ascertainment methods, relying upon normal channels of certificate handling. If the results of the analysis of the full year fail to show an excess in fetal deaths, or if an excess is found but no causal pattern is evident, then we recommend a return to routine monitoring.

The cluster investigation team also recommends continuation of the development of the Cowlitz County Child Death Review Team. When fully implemented, this process may be well positioned for early detection of clusters and able to identify possible preventive interventions.

Finally, the cluster investigation team also recommends continuation of the community programs aimed at improving and promoting healthy pregnancies. There is much that individuals and communities can do to promote healthy mothers and healthy babies, and this work is an essential foundation for the health of the public. On 1 October 1999, during our investigation, the federal Centers for Disease Control and Prevention (CDC) released a report entitled "Achievements in Public Health, 1900-1999: Healthier Mothers and Babies" in its weekly newsletter *MMWR* (available on the World-Wide Web at http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4838a2.htm), containing a list of 17 specific "Prevention measures to reduce maternal and infant mortality and to

promote the health of all childbearing-aged women and their newborns" (attached). This list of 17 items was reprinted in the Longview *Daily News* on 6 December 1999. We encourage the medical community, in partnership with non-medical community organizations and the Cowlitz County Health Department, to examine the extent to which these measures are being taken in Cowlitz County. Where gaps in prevention are found, opportunities exist to improve reproductive health.

Date of report: 13 January 2000.

CDC Recommended prevention measures

Opportunities to Reduce Maternal and Infant Mortality

Prevention measures to reduce maternal and infant mortality and to promote the health of all childbearing-aged women and their newborns should start before conception and continue through the postpartum period. Some of these prevention measures include the following:

Before conception

- Screen women for health risks and pre-existing chronic conditions such as diabetes, hypertension, and sexually transmitted diseases.
- Counsel women about contraception and provide access to effective family planning services (to prevent unintended pregnancies and unnecessary abortions).
- Counsel women about the benefits of good nutrition; encourage women especially
 to consume adequate amounts of folic acid supplements (to prevent neural tube
 defects) and iron.
- Advise women to avoid alcohol, tobacco, and illicit drugs.
- Advise women about the value of regular physical exercise.

During pregnancy

- Provide women with early access to high-quality care throughout pregnancy, labor, and delivery. Such care includes risk-appropriate care, treatment for complications, and the use of antenatal corticosteroids when appropriate.
- Monitor and, when appropriate, treat pre-existing chronic conditions.
- Screen for and, when appropriate, treat reproductive tract infections including bacterial vaginosis, group B streptococcus infections, and human immunodeficiency virus.
- Vaccinate women against influenza, if appropriate.
- Continue counseling against use of tobacco, alcohol, and illicit drugs.
- Continue counseling about nutrition and physical exercise.
- Educate women about the early signs of pregnancy-related problems.

During postpartum period

- Vaccinate newborns at age-appropriate times.
- Provide information about well-baby care and benefits of breastfeeding.
- Warn parents about exposing infants to secondhand smoke.
- Counsel parents about placing infants to sleep on their backs.
- Educate parents about how to protect their infants from exposure to infectious diseases and harmful substances.

Source: CDC. Achievements in Public Health, 1900-1999: Healthier Mothers and Babies. *MMWR* 1999; 48(38);849-858.

http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4838a2bx2.htm